



General Assembly

Substitute Bill No. 1049

January Session, 2009

* SB01049PH 032309 *

**AN ACT PROHIBITING CERTAIN GIFTS FROM PHARMACEUTICAL
AND MEDICAL DEVICE COMPANIES TO HEALTH CARE PROVIDERS.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2009*) As used in sections 1 to 5,
2 inclusive, of this act:

3 (1) "Biologic" means a "biological product", as defined in 42 USC
4 262(i), as amended from time to time, that is regulated as a drug under
5 the federal Food, Drug and Cosmetic Act 21 USC 301 et seq.;

6 (2) "Clinical trial" means a research project involving a drug or
7 medical device that uses volunteer human research subjects to evaluate
8 the safety or effectiveness of such drug or medical device in the
9 screening, prevention, diagnosis, evaluation or treatment of a disease
10 or health condition, or to evaluate the safety or efficacy of the drug or
11 medical device in comparison with other therapies, and that has been
12 approved by the federal Food and Drug Administration or has been
13 approved by a duly constituted Institutional Review Board after
14 reviewing and evaluating such research project in accordance with the
15 human subject protection standards set forth at 21 CFR 50, 45 CFR 46,
16 or an equivalent set of standards of another federal agency;

17 (3) "Health care provider" means a person licensed under title 20 of
18 the general statutes who may prescribe, dispense and administer

19 drugs, or an officer, employee, agent or contractor of such person
20 acting in the course and scope of such person's employment, agency or
21 contract related to, or in support of, the provision of health care, but
22 excludes an employee of a pharmaceutical or medical device
23 manufacturer;

24 (4) "Medical device" means an instrument, apparatus, implement,
25 machine, contrivance, implant, in-vitro reagent or other similar or
26 related article, including any component, part or accessory, that is: (A)
27 Recognized in the United States Pharmacopeia-National Formulary, or
28 any supplement thereto; (B) intended for use in the diagnosis of
29 disease or other conditions, or in the cure, mitigation, treatment or
30 prevention of disease, in persons or animals; or (C) intended to affect
31 the structure or function of the body of a person or animal, and that
32 does not achieve its primary intended purposes through chemical
33 action within or on such body and that is not dependent upon being
34 metabolized for the achievement of its primary intended purposes;

35 (5) "Pharmaceutical or medical device manufacturing company"
36 means any entity that does business, either directly or indirectly, with
37 the state as relates to the purchase of, or the provision of
38 reimbursement for pharmaceuticals, biologics or medical devices,
39 utilized in connection with a state program, including, but not limited
40 to, the Medicaid program, state-administered general assistance
41 program, HUSKY Plan, Part A or Part B, Charter Oak Health Plan, the
42 Department of Correction's inmate health services program and the
43 state employee health insurance plan and is engaged in (A) the
44 production, preparation, propagation, compounding, conversion or
45 processing of legend drugs, biologics or medical devices, either
46 directly or indirectly, by extraction from substances of natural origin,
47 or independently by means of chemical synthesis or by a combination
48 of extraction and chemical synthesis; or (B) the packaging,
49 repackaging, labeling, relabeling or distribution of legend drugs,
50 biologics or medical devices; but excluding a hospital, as defined in
51 section 19a-490 of the general statutes, or a pharmacy licensed
52 pursuant to section 20-594 of the general statutes;

53 (6) "Legend drug" means a drug that is required by any applicable
54 federal or state law to be dispensed pursuant only to a prescription or
55 is restricted to use by prescribing practitioners only, or means a drug
56 that, under federal law, is required to bear either of the following
57 legends: (A) "RX ONLY" IN ACCORDANCE WITH GUIDELINES
58 ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC
59 ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG
60 FOR USE BY OR ON THE ORDER OF A LICENSED
61 VETERINARIAN"; and

62 (7) "Research project" means a project that constitutes a systematic
63 investigation designed to develop or contribute to general knowledge
64 when the results of such project can be published freely by the
65 investigator and such project reasonably may be considered to be of
66 significant interest or value to the scientific community or health care
67 providers working in the particular field of inquiry.

68 Sec. 2. (NEW) (*Effective October 1, 2009*) No pharmaceutical or
69 medical device manufacturing company shall provide or pay for any
70 food or beverage, or both, to any health care provider. Nothing in this
71 section shall prohibit a continuing medical education provider or
72 conference or meeting organizer from allocating any financial support
73 provided by a pharmaceutical or medical device manufacturing
74 company for the event to pay for food or beverage, or both, for all
75 participants in accordance with the provisions of subdivision (3) of
76 subsection (d) of section 3 of this act.

77 Sec. 3. (NEW) (*Effective October 1, 2009*) (a) Except as provided in
78 subsection (d) of this section, no pharmaceutical or medical device
79 manufacturing company shall provide or pay, either directly to a
80 health care provider or indirectly to an event sponsor, for the costs of
81 travel, lodging, time spent or other personal expenses of such health
82 care provider as relate to the attendance of such health care provider at
83 any continuing medical education event, third-party scientific or
84 educational conference or a professional meeting.

85 (b) A pharmaceutical or medical device manufacturing company
86 shall separate all continuing medical education grant-making functions
87 in the state from the sales and marketing departments of such
88 company. Any decision concerning grants shall be made without
89 regard to the sales and marketing objectives of the company.

90 (c) A pharmaceutical or medical device manufacturing company
91 shall not provide any advice or guidance to a continuing medical
92 education provider, even if such advice or guidance is requested by
93 the provider, concerning the content or faculty for a particular
94 continuing medical education program in the state that is funded by
95 such company.

96 (d) Nothing in this section shall prohibit a pharmaceutical or
97 medical device manufacturing company from providing or paying for:

98 (1) Financial assistance for scholarships or other educational funds
99 to permit medical students, residents, fellows and other health care
100 professionals in training to attend educational conferences, provided:
101 (A) The educational conference is a major educational, scientific or
102 policy-making meeting of a national, regional or specialty medical
103 association; (B) the selection of individuals who receive funds is made
104 by the academic or training institution; and (C) no grants, scholarships,
105 subsidies, support, consulting contracts or educational or practice
106 related items are provided or offered to an individual attending such
107 conference in exchange for prescribing, disbursing or using legend
108 drugs, biologics or medical devices or for a commitment to continue
109 prescribing, disbursing or using legend drugs, biologics or medical
110 devices;

111 (2) Compensation or reimbursement to a health care provider
112 serving as a speaker or providing such other actual and substantive
113 services as a faculty organizer or academic program consultant for a
114 continuing medical education event, third-party scientific or
115 educational conference or professional meeting, provided the
116 payment: (A) Is reasonable; (B) is based on fair market value of the

117 services actually rendered by the health care provider; and (C)
118 complies with the Accreditation Council for Continuing Medical
119 Education's Standards For Commercial Support, or equivalent
120 commercial support standards of the relevant continuing education
121 accrediting body;

122 (3) Sponsorship or payment for any portion of the costs of a third-
123 party scientific or educational conference, charitable conference or
124 meeting or professional meeting, where (A) the payment is made
125 directly to the conference or meeting organizer; (B) responsibility for
126 and control over the selection of content, faculty, educational methods,
127 materials and venue belongs to the organizer of the conference or
128 meeting in accordance with the organizer's written guidelines; (C) such
129 conference or meeting is held in a venue that is appropriate and
130 conducive to informational communication and training about medical
131 information; (D) such conference or meeting is primarily dedicated, in
132 both time and effort, to promoting objective scientific and educational
133 activities and discourse with at least one educational presentation
134 being the primary reason for the gathering; and (E) the main purpose
135 for bringing attendees to such conference or meeting is to further their
136 knowledge on the topic or topics being presented; and

137 (4) Sponsorship or other form of payment for any of the costs of a
138 continuing medical education event provided such sponsorship or
139 payment meets the Accreditation Council for Continuing Medical
140 Education's Standards For Commercial Support or equivalent
141 commercial support standards of the relevant continuing education
142 accrediting body, and that no such sponsorship or payment is made
143 directly to a health care provider.

144 Sec. 4. (NEW) (*Effective October 1, 2009*) (a) Except as provided in
145 subsection (b) of this section, no pharmaceutical or medical device
146 manufacturing company shall: (1) Provide a health care provider with
147 entertainment or recreational items of any value, including, but not
148 limited to, tickets to performing arts or sporting events, theater,
149 sporting equipment or leisure or vacation trips; (2) make cash or cash

150 equivalent payments of any kind to a health care provider, either
151 directly or indirectly; (3) provide a health care provider with tangible
152 items of any value other than those permitted pursuant to this section
153 and sections 2 and 3 of this act; (4) provide a health care provider with
154 any grants, scholarships, subsidies, consulting contracts or educational
155 or practice related items in exchange for prescribing, disbursing or
156 using legend drugs, biologics or medical devices or for a commitment
157 to continue prescribing, disbursing or using legend drugs, biologics or
158 medical devices; or (5) provide a health care provider with
159 remuneration, in cash or in kind, directly or indirectly, that is
160 prohibited under applicable state or federal law, including, but not
161 limited to, section 53a-161d of the general statutes, and 42 USC 1320a-
162 7b, including any rebate or kickback.

163 (b) A pharmaceutical or medical device manufacturing company
164 may: (1) Provide reasonable compensation for the professional or
165 consulting services of a health care provider in connection with a
166 research project or clinical trial, or reimbursement of other reasonable
167 out-of-pocket costs incurred by such health care provider directly as a
168 result of the performance of such services, where the compensation or
169 reimbursement is specified in, and paid for under, a written
170 agreement; (2) provide reasonable compensation for expenses,
171 including, but not limited to, travel and lodging, necessary for
172 technical training of health care providers on the use of a medical
173 device where the compensation is specified in, and paid for under, a
174 written agreement; (3) provide, distribute, disseminate or receive peer
175 reviewed academic, scientific or clinical information; (4) purchase
176 advertising in peer reviewed academic, scientific or clinical journals;
177 (5) provide legend drugs or medical device demonstration and
178 evaluation units or educational materials concerning such drugs or
179 units to a health care provider for the beneficial use and education of a
180 health care provider or the patients of such provider; (6) provide price
181 concessions, such as rebates or discounts, consistent with the lawful
182 general practice of the manufacturer or the industry; (7) provide
183 information regarding legend drugs or medical devices, including: (A)

184 Identification of appropriate coverage, coding or billing of such drugs
185 and devices; (B) identification of computerized applications that
186 support accurate and responsible billing to Medicare and other payors
187 for such drugs and devices; and (C) information designed to offer
188 technical or other support concerning the appropriate and efficient use
189 or installation of such computerized applications, provided such
190 technical or other support is not offered for the purpose of inducing a
191 health care provider to purchase, lease, recommend or use such
192 computerized applications; (8) provide payments or free outpatient
193 legend drugs to health care providers for the benefit of low income
194 individuals through an established patient assistance program,
195 provided such program meets the criterion for a permissible program
196 described in Advisory Opinion No. 06-03, issued by the United States
197 Department of Health and Human Services Office of the Inspector
198 General on April 18, 2006, or is otherwise permitted under applicable
199 federal law and regulation including 42 USC 1320a-7b; (9) provide
200 reasonable compensation, based on the fair market value, to a health
201 care provider for consulting services, including, but not limited to, (A)
202 research; (B) participation on a health care related advisory board; (C)
203 collaboration with a nonprofit organization under the provisions of
204 Section 501(c)(3) of the federal Internal Revenue Code of 1986, or any
205 subsequent corresponding internal revenue code of the United States,
206 as from time to time amended, dedicated to the promotion of health
207 and the prevention of disease; and (D) presentations at training
208 programs sponsored by a legend drug or medical device
209 manufacturer, including education and training required by the
210 federal Food and Drug Administration, concerning the development of
211 safe and effective medical devices, where the compensation and
212 reimbursement is specified in, and paid for pursuant to a written
213 agreement. Such written agreement shall document the legitimate
214 need for the consulting services and identify in advance of the
215 provision of such consulting services the connection between the
216 competence and expertise of the health care provider and the services
217 rendered under the agreement. The number of health care providers
218 retained for such project shall not be greater than the number

219 reasonably necessary to achieve the identified purpose. The entity
220 contracting with the health care provider for such consulting services
221 shall maintain records concerning the consulting services and shall
222 make appropriate use of such services. The venue and circumstances
223 of any meeting related to the provision of consulting services shall be
224 conducive to the consulting services and activities related to the
225 services shall be the primary focus of the meeting; or (10) provide
226 reasonable compensation to a health care provider, based on fair
227 market value, for the licensing of intellectual property where the
228 compensation and reimbursement is specified in, and paid for under, a
229 written agreement.

230 Sec. 5. (NEW) (*Effective October 1, 2009*) If a pharmaceutical or
231 medical device manufacturing company provides compensation or
232 reimbursement to a health care provider, in accordance with the
233 provisions of subdivision (2) of subsection (d) of section 3 of this act or
234 subsection (b) of section 4 of this act, and such compensation or
235 reimbursement exceeds one thousand dollars for the calendar year,
236 such company shall disclose, on a form prescribed by the office of the
237 Attorney General, the aggregate compensation or reimbursement
238 provided by such company to the health care provider during the
239 calendar year. The information provided on such form shall include,
240 but not be limited to, the name, address and institutional affiliation of
241 the health care provider and a description of the reason for such
242 payment. Such form shall be filed electronically with the office of the
243 Attorney General on or before July 1, 2010, and annually thereafter, in
244 a format that allows for the searching of individual health care
245 providers or institutional affiliation. The office of the Attorney General
246 shall, within existing budgetary resources, make available on its web
247 site the information contained in such forms.

248 Sec. 6. (NEW) (*Effective October 1, 2009*) A violation of any provision
249 of sections 2 to 5, inclusive, of this act shall constitute an unfair and
250 deceptive trade practice under subsection (a) of section 42-110b of the
251 general statutes.

This act shall take effect as follows and shall amend the following sections:

Section 1	<i>October 1, 2009</i>	New section
Sec. 2	<i>October 1, 2009</i>	New section
Sec. 3	<i>October 1, 2009</i>	New section
Sec. 4	<i>October 1, 2009</i>	New section
Sec. 5	<i>October 1, 2009</i>	New section
Sec. 6	<i>October 1, 2009</i>	New section

PH *Joint Favorable Subst.*